7.0 HUMAN HEALTH BASELINE RISK ASSESSMENT

The purpose of the human health baseline risk assessment (BRA) is to assess the potential for adverse effects associated with exposure to contaminants present at the *[unit name]*. Baseline human health risks are those risks to human health that can be anticipated to be present in the absence of any remedial efforts or institutional controls at the *[unit]*. The BRA provides the basis for determining whether remedial action is necessary and provides the justification for performing remedial actions.

7.1 Description of the Human Health Risk Assessment Process

The human health risk assessment process includes a screening step for the constituents of potential concern (COPCs), an exposure assessment, a toxicity assessment, and a risk characterization. Constituents of concern (COCs) determined during the risk characterization step are carried forward to a weight-of-evidence evaluation in Section 9. Remedial Goal Options (RGOs) are developed in Section 10 for the list of refined COCs (RCOCs) remaining after the weight-of-evidence analysis. The RCOCs become the basis for and the focus of remediation. Each of these steps is discussed in further detail in the following sections and illustrated by the flowchart in Figure 7.1.1-1.

Protocols used in this document are listed in Appendix A. The protocols are based on the latest available United States Environmental Protection Agency (US EPA) guidance as well as on input from the staff of US EPA and the South Carolina Department of Health and Environmental Control (SCDHEC). *Risk Assessment Guidance for Superfund (RAGS) Part D* (EPA 1998) standard tables have been prepared to clearly and consistently document risk parameters, data, calculations, and conclusions from all stages of the human health risk assessment development. Per US EPA guidance, only minor modifications to these tables are allowed because the electronic submittal must be compatible with the US EPA translation software. In order to comply with both the US EPA RAGS Part D requirements and approved Savannah River Site (SRS) protocols for risk assessment development, additional modifications to the tables were required. These changes are documented in Table 7.1-1.

7.1.1 Overview

The human health risk assessment characterizes both the potential risk from exposure to carcinogenic substances and adverse health effects from noncarcinogens to human receptors exposed to unit-related constituents under current and future land use conditions. The US EPA *Risk Assessment Guidance for Superfund* (RAGS) (EPA 1989a), Region IV *Supplemental Guidance to RAGS* (EPA 1995d), and *RAGS Part D – Standardized Planning, Reporting, and Review of Superfund Risk Assessments* (EPA 1998) are used as the primary guidance documents for the human health risk assessment. The methodology used in this assessment is developed in accordance with the Savannah River Site Federal Facility Agreement Implementation Plan (WSRC 1996), as modified in approved Resource Conservation and Recovery Act (RCRA) Facility Investigation (RI/RFI) Baseline Risk Assessment (BRA) protocols. Using this process, the human health risk assessment has been organized into the following sections:

- Human Health Constituents of Potential Concern (Section 7.2)

  [Includes RAGS Part D Standard Table 1 – Selection of Exposure Pathways]

  [Includes RAGS Part D Standard Table 2 – Occurrence, Distribution, and Selection of Chemicals of Potential Concern]

  [Includes RAGS Part D Data Usability Worksheet]

- Exposure Assessment (Section 7.3)

  [Includes RAGS Part D Standard Table 3 – Medium-Specific Exposure Point Concentration Summary]

  [Includes RAGS Part D Standard Table 4 – Values Used for Daily Intake Calculations]

- Toxicity Assessment (Section 7.4)

  [Includes RAGS Part D Standard Table 5 – Non-Cancer Toxicity Data]

  [Includes RAGS Part D Standard Table 6 – Cancer Toxicity Data]

- Human Health Risk Estimation (Section 7.5)

  [Includes RAGS Part D Standard Table 7 – Calculation of Non-Cancer Hazards]

  [Includes RAGS Part D Standard Table 8 – Calculation of Cancer Risks]

- Human Health Risk Assessment Results (Section 7.6)

  [Includes RAGS Part D Standard Table 9 – Summary of Receptor Risks and Hazards for COPCs]

  [Includes RAGS Part D Standard Table 10 – Risk Assessment Summary]

7.1.2 Receptors and Exposure Scenarios

7.1.2.1 Land Use Assumptions and Potentially Exposed Receptors

The following section describes land uses at the *[waste unit]* and the human receptors that may be exposed to unit-related constituents. Potential receptors are expected to differ for the current and future land use scenarios. The possible receptor*[s]* under the current land use include the known on-unit worker *[and trespasser, where applicable]*. The possible receptors under the future land use include the hypothetical on-unit industrial worker and the hypothetical on-unit residents (adult and child). *[Other exposure scenarios may be evaluated on a unit-specific basis.]*

7.1.2.1.1 Current Land Use

[The following paragraph is provided as an example. Unit-specific language shall be developed for each project.]

Currently, the [waste unit] is [active/inactive]. Access to the SRS is controlled by the DOE. Once within the SRS boundaries, access to the [waste unit] [is/is not] restricted. A locked gate exists at the unpaved road leading to the [waste unit], to prevent vehicular access. Access on foot is easy and unrestricted. The area surrounding the [waste unit] is undeveloped and wooded. No evidence of casual trespassing (e.g., people, litter, or campsites) was observed during a unit visit. Groundwater near the [waste unit] is not currently being used for consumption by on-unit workers. The potentially exposed receptors that are evaluated for the current land use scenario are the known on-unit workers [identify other receptors, as applicable].

A current on-unit worker may be a researcher, environmental sampler, or personnel in close proximity to the unit.

<u>Known On-Unit Worker</u>

The current population that potentially could be receptors for exposure to constituents associated with the *[waste unit]* is the known on-unit worker who comes to the area on an infrequent or occasional basis. Known on-unit workers are defined as SRS employees who work at or in the vicinity of the *[waste unit]* under current land use conditions . A known on-unit worker may be a researcher, environmental sampler, or other SRS personnel in close proximity to the unit Although these receptors may be involved in the excavation or collection of contaminated media, they would be using SRS procedures and protocols for sampling at hazardous waste units. *[Revise this paragraph, as necessary, to reflect actual unit-conditions. For example, the known on-unit worker may have more than casual access, depending on the unit-specific conditions (e.g., within a waste unit fenceline vs. no fence.). For the [unit] the on-unit worker was considered to be a groundwater sampler...]*

7.1.2.1.2 Future Land Use

Specific for the waste unit. The following paragraph is provided as an example.

According to the *Savannah River Site: Future Use Project Report* (DOE 1996), "residential uses of SRS land should be prohibited." [*Insert unit-specific discussion here such as the following: "In this report the TNXOU is identified as a "current industrial (with buffer)" area. The future use recommendation contained in the report is for "future industrial (non-nuclear)". [INCLUDE A DISCUSSION SIMILAR TO THE FOLLOWING EXAMPLE: The potential future uses of this unit are as a research and development (pilot scale) industrial facility and possibly as an industrial manufacturing facility. No residential use of this waste unit is anticipated for the future, however, trespasser and residential land use scenarios will be evaluated for comparison purposes due to the proximity (← mile) of the TNX area to the site boundary and Savannah River.]*

If land use conditions remain industrial, the only future human receptors are considered to be industrial workers. However, until deed notifications are established, the possibility exists that new buildings could be constructed and the area at or near the [waste unit] could be converted to residential use in the future. Although residential development is unlikely, a hypothetical residential exposure scenario for both adults and children is presented for comparative purposes. This is in accordance with US EPA Region IV guidance (EPA 1995d) which states that residential development cannot be entirely ruled out. However, the future use of the land is not likely to change from current use.

The potentially exposed receptors that are evaluated for the future land use scenario include the hypothetical on-unit industrial worker (adult) and hypothetical on-unit resident (adult and child). *[Add others, as applicable]*

<u>Hypothetical On-Unit Industrial Worker</u>

The hypothetical on-unit industrial exposure scenario addresses long-term risks to workers who are exposed to unit-related constituents while working within an industrial setting. The hypothetical on-unit industrial worker is an adult who works in an outdoor industrial setting that is in direct proximity to the contaminated media for the majority of his time.

<u>Hypothetical On-Unit Resident (Adult and Child)</u>

The hypothetical on-unit resident exposure scenario evaluates long term risks to individuals expected to have unrestricted use of the unit. It assumes that residents live on-unit and are chronically exposed (both indoors and outdoors) to unit-related constituents. The hypothetical on-unit resident includes adults and children who are exposed to all the contaminated media. As noted above, for all noncarcinogenic exposures to residents, a child and an adult are the receptors that are evaluated. For all carcinogenic exposures to residents, a weighted-average child/adult is evaluated. This scenario assumes that children in the first six years of life are a more sensitive sub-population and, therefore, assigns a greater weight to this proportion of the 70-year lifetime exposure. *[This scenario may also include an adolescent child for ages 7 through 14.]*

[Other hypothetical future use scenarios (e.g., Off-SRS resident, trespasser, recreational etc.) may be warranted at a given waste unit, but must be approved by the WSRC human health technical lead.]

7.1.3 Exposure Routes

Exposure routes describe the way a chemical or physical agent comes into contact with a receptor (i.e. by ingestion, inhalation, dermal). Exposure points are locations where contact between contaminant and receptors may occur. If a complete exposure route is suspected, the exposure assessment attempts to quantify contaminant concentrations and uptake at the exposure point. Hazard and risk estimates are then calculated for exposures occurring to environmental media at the exposure point via the relevant exposure routes. Identified below are the probable exposure routes for the *[waste unit*] based on the contaminated media and anticipated activities at the exposure points.

- Ingestion *(soil, water, biota, etc.)*
- Inhalation (of particles and vapors)
- Dermal exposure *(soil, water, etc.)*
- *External Radiation (from surface soil)*

These scenarios are discussed in detail in the latest revision of the <u>Development of Exposure Groups Protocol</u>.

7.1.4 Exposure Groups

Media of potential concern are defined as any medium through which human or ecological receptors may be exposed to constituents or through which constituents may be transported to potential receptors. During the unit investigation, constituent concentrations were determined for a variety of media including *groundwater, soil, sediment, and surface water [revise media as necessary]*. The data for each medium are sorted and grouped into exposure groups in order to provide a set of values (data set) for further processing. That is, the available data for each medium are assigned to either a *groundwater, soil, sediment or surface water exposure group [revise media as necessary]*.

An exposure group consisting of data for the 0 to 0.3 m (0 to 1 ft) soil interval is established for actual current conditions, and an exposure group for the 0 to 1.2 m (0 to 4 ft) soils interval is established to account for a hypothetical future scenario in which subsurface soils are excavated and brought to the surface. Because institutional controls preventing the excavation of contaminated soils cannot be guaranteed, the future scenario assumes the possible excavation of soils from depths of 0 to 1.3 m (0-4 ft) and subsequent spreading of those soils on the surface as the result of construction activities. Approximately 1.3 meters (4 ft) is considered a reasonable depth for a residential contractor to excavate during typical construction in the SRS area. *[These intervals may changed based on unit-specific data. The 0-4' interval may not be considered for every unit]*.

For the *[unit name]*, the following exposure groups are identified for human receptors:

1) *Unit-Source*

- *Soil from 0 to 1 foot, over the area of the unit.*
- *Soil from 0 to 4 feet, over the area of the unit.*
- *Groundwater in a designated aquifer system (may be in the highly concentrated area of the plume, if appropriate).*
- *Surface Water in a nearby water system.*
- *Sediments / soils in nearby drainage areas.*

2) *Unit-Background*

- *Soil from 0 to 1 foot*
- *Soil from 0 to 4 feet*
- *Soil from 0 to X feet, where X represents the depth of the vadose zone investigated.*
- *Groundwater in a designated aquifer system.*
- *Surface Water in a nearby water system.*

Sediments / soils in nearby drainage areas. [Include all unit and background exposure groups as appropriate, e.g., surface and subsurface soils, surface water, sediment, groundwater, etc.)

The sample intervals collected and analyzed are in compliance with the Resource Conservation and Recovery Act (RCRA) Facility Investigation/Remedial Investigation (RFI/RI) Work Plan for the *[unit name]*. The environmental data used in the risk assessment, including the sample interval, sample location, and sample identification numbers can be found in the *[unit name]* Field Characterization Report (WSRC, *[YEAR]*) *[Revise report name, as necessary.]*

7.1.5 Exposure Pathways

7.1.5.1 Identification of Potential Human Exposure Pathways

Exposure pathways describe "the course a chemical or physical agent takes from the source to the exposed individual" (EPA 1989a). Four components comprise an exposure pathway:

- Source (landfill, spill, etc.)
- Exposure media (groundwater, air, etc.)
- Exposure point (drinking water well, shower, etc.)
- Exposure route (e.g., ingestion, dermal contact, and inhalation)
- Receptor (resident, worker, etc.)

If any of these elements are missing, the pathway is incomplete and not considered further in the risk assessment. A pathway is complete when all five elements are present to permit potential exposure of a receptor to a source of contamination. Quantification of some potentially complete pathways may not be warranted because of the minimal contribution to risk relative to other major pathways. The dominant exposure pathways from constituent sources and exposure media to human receptors potentially exposed to COPCs at the unit are presented in Table 7.1.5.1 and in a pictorial representation in Figure 7.1.5-X. As shown in the conceptual site model (CSM) (Figure 7.1.5-X*), [soil, groundwater, surface water, sediment, and food chain*] exposure routes are considered in the human health risk assessment.

Exposure analysis is conceptually important in terms of identifying all potentially complete exposure routes, in understanding the nature and extent (as well as fate and transport) of contamination, and for developing preliminary remedial alternatives. In a complete pathway, exposure occurs at exposure points that may represent only a small portion of the entire exposure route. If there is no exposure point, then there is no exposure, even if contaminants have been released into the environment. The potentially complete pathway for each receptor is provided below.

<u>Known On-Unit Worker</u>

The primary exposure routes proposed for the evaluation relative to the known on-unit worker:

- *Exposure to contaminated soils through ingestion, dermal contact, inhalation of windblown dust and volatile organics in air, and direct radiation*
- *Exposure to contaminated surface water and sediment through ... [should be evaluated on a unit-specific basis]*
- *[Discuss other exposures, as applicable]*

A drinking water pathway is not credible for the known on-unit worker since shallow groundwater is not used as a source of drinking water at SRS. *[Discuss other exposure pathways that may not be realistic for a receptor, as applicable).*

<u>Hypothetical On-Unit Industrial Worker</u>

The primary exposure routes proposed for the evaluation relative to the hypothetical on-unit industrial worker include:

- *Exposure to soils through incidental ingestion, inhalation of windblown dust and volatile organics in air, dermal contact, and direct radiation.*
- *Exposure to groundwater through ingestion of drinking water from contaminated sources*.
- *Exposure to contaminated surface water and sediment through ... [should be evaluated on a unit-specific basis]*

- *[Discuss other exposures, as applicable]*

<u>Hypothetical On-Unit Resident (Adult & Child)</u>

The primary exposure routes proposed for the evaluation relative to the hypothetical on-unit resident include:

- *Exposure to contaminated soils through incidental ingestion, inhalation of windblown dust and volatile organics in air, dermal contact, direct radiation, and ingestion of homegrown produce.*
- *Exposure to groundwater through ingestion and showering.*
- *Exposure to surface water and sediment through dermal contact.*
- *[Discuss other exposures, as applicable]*

Following US EPA Region IV guidance (EPA 1995d) ingestion exposures are not expected for ingestion of sediments since surface water covers sediments the majority of the year. Exposure to surface water could occur while wading, which is considered more realistic than swimming for this unit. [This paragraph should be revised as necessary to reflect actual unit-specific conditions.]

7.2 Human Health Constituents of Potential Concern

7.2.1 COPC Selection Process Description

The objective of constituent selection is to identify constituents of potential concern (COPCs) and focus subsequent efforts in the risk assessment process. COPCs are defined as constituents that are potentially unit-related and are present at concentrations that may negatively impact human health and/or the environment. COPCs are selected in accordance with guidance from US EPA Headquarters (EPA, 1989), EPA Region IV (EPA, 1995), and the South Carolina Department of Health and Environmental Control (SCDHEC), and are quantitatively carried through the risk assessment. In order to meet the remedial action objectives (RAO) of preventing human exposure to unacceptable levels of contamination, the BRA strategy will be to identify the COPCs for the unit based on complete exposure pathways and then to evaluate the risk potential of the human health COPCs.

The COPC selection process is developed for the COPC screening and is based only on complete exposure pathways. The conceptual site models (CSMs) for the *[unit name]* summarize the establishment of credible exposure scenarios that identify exposure routes and media of potential concern for both human and ecological receptors. The CSM is discussed in detail in Section 2.0. A pictorial representation of receptors and exposure pathways is presented in Figure 7.1.5-X.

The following information details the process applied for determining media exposure groups and COPCs used in the BRA. Exposure groups and COPC selection were determined per Development of Exposure Groups Protocol (ref) and Human Health Constituents of Potential Concern Protocol (ref). Note the difference in the processes for determining unit-related constituents (USCs) used in the earlier sections of the RFI/RI/BRA for the purpose of documenting the nature and extent of contamination**.** For Sections 7.2.1.1 and 7.2.1.2, individual steps are annotated alphabetically to correspond with Figure 7.2.1-1.

7.2.1.1 Initial COPC and Exposure Route Processing Steps (Steps A)

A.1 The data for the detected constituents are sorted and grouped by medium and exposure group as described in Section 7.1.5. The appropriate set of composite background data for each medium and exposure group is then identified. Specifically, for the 0 to 0.3 m (0 to 1 ft) unit soil exposure group, background samples from the same soil interval are used to calculate average background concentrations. All other soil exposure groups, background data collected from all depths sampled from 0 to X.X m (0 to X ft) are pooled to calculate the average background concentrations. Data that have qualifiers are evaluated to determine whether the qualified data should be retained and how it should be treated.

All qualifiers are addressed before the constituent is used or deleted from the quantitative risk assessment. Qualifiers used by the laboratory may differ from those used in the data validation process in both identity and meaning. Therefore, definitions for all qualifiers are reviewed in the *Data Summary Report for the [unit name], Phase I (WSRC, 19XX)* prior to data evaluation.

A.2 For each constituent in each medium or exposure group, constituents are eliminated that have no detects.

A.3 For each constituent in each medium and exposure group, the following parameters are determined:

a. Maximum detected concentration

b. Frequency of detection

c. Two times (2X) average background concentration for 0 to 0.3 m (0 to 1 ft) soil interval, pooled soil intervals for 0 to *[X.X]* m (0 to *[X]* ft), and groundwater. *[Revise intervals, as necessary]*

Chapter 4.0 provides a summary of all data evaluated for the risk assessment. A detailed description of the statistical methods used in evaluation of the data also is provided in Chapter 5.0 along with a statistical summary of data.

7.2.1.2 Human Health COPC and Exposure Route Processing Steps (Steps B)

B.1 A screening is performed against the most current US EPA Region III risk-based concentrations (RBCs), (EPA, 1999*[x]*). Risk-based activities (RBA) are also developed using the US EPA Region III protocol (Risk-Based Activity Calculations for Radionuclides: Residential Water Ingestion, Residential Soil Ingestion, and Residential External Radiation Exposure Pathways, Engineering Calculations Number K-CLC-G-00023, Rev. 3, January 2000). The screening is conducted by comparing the maximum detected concentration or activity of each soil, sediment, surface water, and groundwater analyte to its relevant screening value. For radionuclides in soils, the combined residential ingestion and external exposure RBA is used as the screening criteria. The screening is performed for surface water and groundwater analytes using US EPA Region III RBCs for tap water.

The Region III RBCs are based on a risk level of 1 x 10^{-6} or a hazard quotient (HQ) of 1 (EPA 1999x). Prior to screening, the RBCs for noncarcinogenic effects are adjusted to a HQ of 0.1, which is accomplished by multiplying the RBC screening value for noncarcinogenic effects by 0.1. Noncarcinogenic constituents are retained for further evaluation if the maximum concentrations exceed the 0.1 screening levels. Carcinogenic constituents are retained for further evaluation if the maximum concentrations exceed the 1 x 10^{-6} risk level. The human health screening values (RBC or RBA) are identified in Tables 7.2.2-*[X]* through 7.2.2-*[X]* for the different surface soil, subsurface soil, groundwater, surface water, and sediment exposure groups.

If RBC and RBA values are not available, a surrogate value may be used. The following surrogates were used to screen constituents for which a screening value is not available:

[Insert table of surrogate values with two columns listing the analyte name and the proxy RBC/RBA analyte name.]

Analyte	***Proxy Human Health Screening Analyte Name***
2-Nitrophenol	*4-Nitrophenol*
Etc	*etc*

If no surrogate value can be determined, the constituent is identified in the uncertainty discussion as a constituent for which a risk evaluation could not be performed and the potential risks are qualitatively discussed.

B.2 The following list of human health essential nutrients detected at the unit are not considered to be toxic and do not have health based limits and are, therefore, excluded from the COPC screening process: calcium, chloride, iodine, magnesium, phosphorous, potassium, and sodium.

B.3. Anthropogenic (man-made) constituents that exceed the RBC or RBA screening step are identified as COPCs and are carried forward for a more detailed analysis of human health risk. Anthropogenic constituents are not screened against 2 times (2X) the unit background average concentration.

For the naturally occurring constituents that exceed the RBC or RBA screening level in step B.1, the maximum concentration is compared to 2X the unit-background average concentration for each exposure group. (For soils, the 0 to 0.3 m [0-1 ft] unit maximum value is compared to the 0 to 0.3 m [0-1 ft] unit-background average value; the 0 to 1.2 m [0-4 ft] interval is compared to the pooled average background value for all soil depths). The average concentration for nonradioactive constituents in the background data set is determined using the detected values and surrogate value of one-half the method detection limit (1/2 MDL) for non-detected constituents. For radioactive constituents, the average activity in the background data set is determined using the reported activity for constituents with activities above the method detectable activity (MDA), and a surrogate value of one-half the method detectable activity (1/2 MDA) for constituents with activities below the MDA. The comparison is made for each medium and exposure group. The constituent is eliminated as a COPC in each medium in which its maximum concentration is less than 2X the unit-background average concentration.

B.4 Previously eliminated constituents, media, or exposure groups are considered for re-inclusion based on historical information or considerations such as mobility, bioaccumulation, persistence, or toxicity. Also, any member of a chemical class that has other members selected as COPCs should be retained [e.g., detected polynuclear aromatic hydrocarbons (PAHs), dioxins, and furans]. No constituents were reincluded based on historical information, mobility, bioaccumulation, persistence, or toxicity for the [unit name]. Some PAHs were reincluded because other members of the same chemical class were retained through the COPC selection process. *[Revise the last two sentences as appropriate for the waste unit]*.

B.5 For each medium and/or exposure group, it is determined whether any COPCs remain. If no COPCs remain, the medium and/or exposure group is removed from further consideration in the human health risk assessment. No medium or exposure group was removed from further consideration for the [unit name]. *[Revise this statement as appropriate for the waste unit]*.

B.6 The constituents and exposure groups that are retained after the application of this process are identified as human health COPCs and will be carried forward into a more detailed analysis of human health risk. Table 7.2.2-*[X]* through Table 7.2.2-*[X]* presents the human health COPCs identified as a result of the screening process.

7.2.2 COPC Screening Results for Unit-Source Data

Summaries of human health COPCs for the various media are presented in Tables *7.2.2-[X]* through 7.2.2-*[X]*. The constituents and exposure pathways that are retained after the application of the screening process are then selected for use as the starting point of the human health risk assessment analyses in Sections 7.5. If no human health-related COPCs or exposure pathways remain upon completion of the screening process, the development of Section 7.5 is not warranted. The assessment of the lack of potential adverse effects associated with exposure to unit-related constituents is complete and the justification for no further action is established. However, for this unit, COPCs are identified at the end of the COPC selection process. [*Revise or delete this statement as appropriate for the waste unit.]*

7.2.3 COPC Screening Results Summary

7.2.3.1 <u>Human Health COPCs and Exposure Pathways</u>

The human health COPC selection process described in section 7.2.1 is used to screen the initial COPCs identified in each exposure group. Tables 7.2.4-[X] through 7.2.4-[X] present a summary of the unit constituents that exceeded both an RBC/RBA level and the 2X average background screen (naturally-occurring constituents), and were retained as human health COPCs.

7.3 Exposure Assessment

The objective of the exposure assessment is to estimate the type and magnitude of the potential human exposures to the COPCs identified in Section 7.2.4. For a given receptor group (i.e., workers, residents), the result is an estimate of chronic daily intake or dose that may occur from exposure to the COPCs in the various environmental media (i.e., soil and groundwater). In identifying primary routes of exposure, current and future land uses of the unit and surrounding area are considered. This section describes land use assumptions, identifies potential receptors, develops information on exposure routes, estimates the concentration of the radioactive and nonradioactive COPCs at points of human exposure, and determines receptor intakes (doses). Reasonable maximum exposure (RME) estimates are presented for radiation doses and chemical intakes within each scenario. They are derived as discussed in Section 7.3.2. The exposure assessment, in conjunction with the subsequent toxicity assessment (discussed in Section 7.4), supports the characterization of potential risks to human health (discussed in Section 7.5). Uncertainties of the exposure assessment are discussed in Section 7.6.

7.3.1 Exposure Point Concentrations

Exposure point concentrations (EPCs) are the concentrations of constituents in a given medium to which human receptors are exposed at the point of contact. Exposure point concentrations are used to calculate the constituent intakes or doses of human receptors based on methodology provided in US EPA risk assessment guidance (EPA 1989 and 1991).

Because of the uncertainty associated with any estimate of exposure concentration, US EPA has selected a highly conservative approach in which the 95% upper confidence limit (95 UCL) on the mean or the maximum constituent concentration (whichever value is lower) is used to determine the exposure concentration in each medium (EPA 1989). This exposure concentration is called the reasonable maximum exposure (RME) concentration. The 95 UCL represents the upper 95^{th} percentile confidence limit on the mean, meaning there is a 95 percent probability that the average exposure point concentration will fall at or below the 95 UCL. Given a large, normally distributed data set, the 95 UCL is expected to be only slightly larger than the mean. If, however, the data set is small, variable, and is not normally distributed, the 95 UCL may be much larger than the mean, and may even exceed the maximum value. Because the 95 UCL is sensitive to the data distribution and the sample number, the smaller of the 95 UCL or maximum detected value is chosen as the RME exposure point concentration.

Tables in Chapter 5.0 (Tables 5.1-*[X]* through 5.1-*[X])* present the 95% UCL and maximum concentrations used in the selection of the RME concentrations. Appendix [X] presents the procedure for calculating the 95% UCL concentration for each medium.

7.3.2 Development of Constituent Intakes

Human intake factors (HIFs) are constituent-specific fators that are calculated based on the RME concentrations for each principal complete pathway. The RMEs represent the highest exposure that is reasonably expected to occur in a small, but definable “high-end” segment of the potentially exposed population. Constituent-specific intakes or dose estimates for nonradioactive and radioactive constituents are calculated for the receptors and exposure routes identified for quantitative evaluation in Section 7.1.5. The RME concentrations and the intakes are calculated using US EPA methodology presented in US EPA's Risk Assessment Guidance for Superfund (EPA 1989a and the Office of Solid Waste and Emergency Response [OSWER] Directive 9285.6-03 [EPA 1991]).

Under the current and future land use scenarios, estimated intakes are calculated for the known on-unit worker, hypothetical on-unit industrial worker, and hypothetical on-unit resident for exposure to constituents in the media previously described in Section 7.1.5. The constituent-specific intakes are developed for the principal complete exposure routes (EPA 1992) and are presented with risk calculations in *Appendices H-M*. The exposure parameters and intake equations are discussed below.

7.3.3 Exposure Factors

Exposure factors or parameters are variables that describe the exposed population such as the contact rate, exposure frequency and duration, and body weight. Exposure factors for a given pathway should be selected so that the combination of all factors results in an estimate of the reasonable maximum exposure for that pathway. The RME exposure factors are calculated by using a combination of high end and central exposure parameters that result in a dose estimate representative of the high end of a population of exposures. In some cases published exposure assumptions are used, and in other best professional judgment is used in the absence of unit-specific data (EPA 1995). Table 7.3.2-*[X]* presents the values used for the exposure parameters and the technical basis on which parameter values are based for each complete exposure pathway. Technical discussion of all exposure parameters and other factors required to calculate risk and hazards are presented in detail in Appendix *[X]*.

7.3.4 Exposure Equations

Table 7.3.2-*[X]* presents the exposure parameters and standard equations used to estimate constituent-specific intake or dose for each exposure pathway. The table includes equations for exposure to *soil (dermal contact and ingestion), groundwater (dermal contact, inhalation and ingestion), air (inhalation of particulates and volatiles), external radiation from soil, and ingestion of homegrown produce. [Add discussions of surface water and sediment, if present.]* A detailed discussion of the exposure parameters is provided in Appendix *[X]*.

7.4 Toxicity Assessment

The toxicity assessment presents and discusses constituent-specific quantitative dose-response data for the COPCs identified in Section 7.2. The objectives of the toxicity assessment are to evaluate the inherent toxicity of the substances under investigation and to identify and select toxicity values for use in risk characterization. For the assessment of human health risks from exposure to chemicals and radionuclides, the following toxicity values are of principal importance:

- Reference doses (RfDs) for oral exposure; acceptable intake values for chronic exposure (noncancer effects)

- Reference concentrations (RfCs) for inhalation exposure; acceptable intake values for chronic exposure (noncancer effects); these have been converted to inhalation RfDs by multiplying by 20 m^3/day and dividing by 70 kg

- Cancer slope factors (CSFs) for oral and inhalation exposure routes; chemicals and radionuclides

- CSFs for the external exposure route: radionuclides

- Dose conversion factors (DCFs) for the oral, inhalation, and external exposure routes: radionuclides

Toxicity information is preferably obtained from the Integrated Risk Information System (IRIS) (EPA 1996). If values are not available from IRIS, the Health Effects Assessment Summary Tables (HEAST) (EPA 1997 *or later version*) or the Superfund Health Risk Technical Support Center-National Center for Environmental Assessment of US EPA (SHRTSC-NCEA) is consulted.

Tables 7.4.1-*[X]* through 7.4.1-*[X]* presents the toxicological data used in the risk assessment for both the nonradiological and radiological COPCs. Appendix F presents the abbreviated toxicity profiles for each chemical and radionuclide COPC. *[The full text of the ATSDR Toxicological Profiles is available in the SRS Administrative Records File.]*

7.4.1 Chemical and Radionuclide Toxicity

7.4.1.1 <u>Chemical Toxicity</u>

7.4.1.1.1 Carcinogens

The CSF is used to estimate an upper-bound probability of an individual developing cancer because of a lifetime of exposure to a particular level of a potential carcinogen. CSF is defined as the probability of a response per unit intake of a chemical over a lifetime (EPA, 1989). Slope factors are typically calculated for potential carcinogens in classes A, B1, and B2. Carcinogen weight-of-evidence classifications are defined in Appendix *[X]*.

Toxicity values for carcinogenic effects can be expressed in several ways. The CSF is usually the upper 95^{th} percent confidence limit of the slope of the dose-response curve and is expressed as $(mg/kg\text{-}day)^{-1}$. Carcinogenic effects also can be expressed in terms of risk per unit concentration of the substance in the medium where human contact occurs. These measures, called unit risks, are calculated by dividing the CSF by 70 kg and multiplying by the inhalation rate (i.e., 20 m^3/day) or the water consumption rate (i.e. 2 liters/day), respectively, for the risk associated with unit concentration in air or water.

Tables 7.4.1-*[X]* through Table 7.1.4-*[X]* provide the CSFs for the oral, dermal, and inhalation exposure pathways.

7.4.1.1.2 Noncarcinogens

A RfD, reported as a chemical intake (mg/kg-day), is the toxicity value used most often in evaluating noncarcinogenic effects. RfDs are developed and verified by US EPA, and are defined as "an estimate of a daily exposure level to a specific constituent for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime" (EPA 1989a). RfCs that are reported as concentration in air (in mg/m^3) are also used to evaluate noncarcinogenic effects. Derivation and/or conversion from a RfC (concentration) to a RfD (dose) are employed.

Tables 7.4.1-*[X]* through Table 7.1.4-*[X]* provides the reference dose values for the oral, dermal, and inhalation exposure pathways.

7.4.1.2 Radiation Toxicity

Radiation exposures can be both internal (as a result of ingestion, inhalation, or dermal absorption) and external (from gamma shine or dermal exposure). In general, external exposures result from radionuclides that emit gamma radiation, which readily penetrates skin and clothing. External sources of alpha and beta radiation are far less penetrating than gamma radiation and deposit their energy primarily on the outer layer of skin or on clothing. Consequently, their contribution to the total external radiation dose absorbed by an individual is negligible compared to that deposited by gamma rays (ATSDR, 1992a and b)

Many alpha-emitting radionuclides (e.g., all radium isotopes except radium-228) or their daughters also emit gamma rays (Turner, 1986). Therefore, external radiation exposure slope factors have been calculated for alpha-emitting isotopes and their daughters.

The risk of developing cancer as a result of internal or external exposure to radionuclides is evaluated using radionuclide CSFs calculated by US EPA's Office of Radiation and Indoor Air (EPA, 1995b). Radionuclide ingestion and inhalation CSFs are best estimates (i.e., median or 50^{th} percentile values) of the age-averaged, lifetime excess cancer incidence (fatal and nonfatal cancer) risk per unit of activity inhaled or ingested, expressed as risk/pCi. External exposure CSFs are best estimates of the lifetime excess cancer incidence risk for each year of exposure to external radiation from gamma-emitting radionuclides distributed uniformly in a thick layer of soil and are expressed as risk/year per pCi/gram of soil (EPA, 1995).

Tables 7.4.1-[X] through Table 7.1.4-[X] provide the radionuclide CSFs for the oral, inhalation, and dermal exposure pathways.

External exposure can also be evaluated as immersion exposures, such as could occur during swimming. For the [waste unit], external radiation exposures include direct exposure from contaminated soil and sediment. For this investigation the external radiation exposure for sediment would differ from that exposure for soil due to the high moisture content of the sediments, which would provide additional shielding from radiation. Direct radiation exposures for sediments were thus evaluated using radiation dose equivalents and published dose conversion factors developed for exposures encountered along the shoreline of a river. Radiation exposures for radionuclides detected in the surface water were not evaluated in the *risk assessment because there are no applicable cancer slope factors. In this regard, the exposures to radionuclides in surface water will be attenuated due to the shielding effects of water. More information regarding estimation of radiation dose equivalent is presented in Section 7.4.2*

7.4.2 Lead

US EPA does not provide a verified RfD or CSF for lead. The evaluation of lead is conducted by first comparing concentrations for each exposure group to the following action levels: 400 mg/kg in soil and 15 μg/L in drinking water (EPA, 1995). If concentrations are less than or equal to these levels or if lead is eliminated in the background comparison, no further evaluation is conducted in accordance with US EPA Region IV guidance (EPA, 1995). If concentrations are greater than these levels, exposures are evaluated in one of two ways. For children, exposures to lead are analyzed by estimating blood lead levels using US EPA's uptake/biokinetic computer program, LEAD 0.99d (EPA, 1994). Because the US EPA model is applicable only to children, a model developed and recommended by US EPA (EPA, 1996) may be used to estimate blood lead levels in adults. *For the [unit], lead was determined to be a COPC in soil; therefore, the lead model was evaluated for exposure of hypothetical on-unit residents. The methodology and numerical and graphical results of the lead model are presented in Appendix [X], or no soil or groundwater lead concentrations exceeded the screening levels at the [waste unit].*

7.4.3 Provisional Values

It is important to note that provisional toxicity values used in the US EPA Region III RBC Tables (EPA 1999) may be adopted for use in the risk assessment. Risk managers should recognize that provisional toxicity values should not be regarded with the same level of confidence as US EPA-verified toxicity values. Provisional toxicity values are alternative values not included in US EPA's IRIS or HEAST databases. Provisional values have a higher degree of uncertainty due to limited data, conflicting results, or other considerations. For example, iron may be identified as a chemical with human health effects exceeding US EPA targets when using provisional toxicity values. The decision to remediate should be tempered with the understanding that the toxicity value for iron is provisional, and represents a low level of quality relative to US EPA-verified toxicity values. *Provisional data was used for [list chemicals] in the risk assessment.*

7.4.4 Constituents for which No US EPA Toxicity Values are Available

US EPA toxicity values are available only for the oral and inhalation exposure routes. As discussed below for the dermal contact route, it is sometimes necessary to convert the administered dose toxicity value to an absorbed dose in order to calculate risk for the dermal exposure route. Additionally, when a constituent has no chronic toxicity values the toxicity value of a constituent that is related both chemically and toxicologically may be used. Section 7.6 discusses the implications of the presence of constituents without toxicity values and their absence from quantitative risk.

7.4.4.1 Constituents Related to the Dermal Contact Route

In accordance with RAGS (EPA, 1989), absorbed-dose toxicity values are derived from the oral administered-dose toxicity values to estimate risk associated with the dermal contact route. Adjustment of the oral administered-dose toxicity values from absorbed-dose toxicity values requires sufficient data from principal laboratory studies on oral absorption efficiency (i.e., gastrointestinal absorption factors) in the species for which the toxicity values are based.

Using these data, the administered-dose toxicity value is multiplied (if it is a RfD) or divided (if it is a CSF) by a gastrointestinal absorption factor to derive a toxicity value based on the absorbed dose. In cases where constituent-specific absorption factors are not available, US EPA Region IV provides default absorption factors of 80 percent for VOCs, 50 percent for semivolatile organic compounds (SVOCs), and 20 percent for inorganic substances (EPA, 1995). Tables 7.4.1-[X] and 7.4.1-[X] present the oral to dermal adjustment factor for noncarcinogens and carcinogens.

7.4.4.2 Constituents Related to the Inhalation Route

Inhalation toxicity values should be used for fugitive dust emissions and chemicals volatilized from soil. US EPA Region IV also recommends the use of inhalation toxicity values for estimates of volatile organic chemical (VOC) exposure from showering (EPA, 1995). Evaluation of the inhalation toxicity value due to exposure during showering is applied to the oral intake value.

7.5 Human Health Risk Estimation

Risk characterization combines exposure intake values and toxicity assessment values to determine a quantitative risk for all human receptors defined in the human health risk assessment. The objective of the human health risk characterization is to determine whether exposure to constituents associated with the unit poses risks that exceed target levels for human health effects. The results of the human health baseline risk assessment support the decision of need for unit remediation.

This section presents the human health cancer risks and constituent hazard estimates for the current land use and hypothetical future scenarios for the unit. Quantitative evaluations of exposure routes for human receptors include a *known on-unit worker, a hypothetical on-unit (industrial) worker, and a hypothetical on-unit resident.* Appendices *H-M* present the constituent-specific risks for each receptor and exposure route. Tables 7.6.1-*[X]* through 7.6.1-*[X]* provide a summary of the risks and hazards for each receptor by medium and exposure route. Tables 7.6.2-*[X]* provide a summary of the risks and hazards for the COCs that will undergo further uncertainty evaluation for the determination of RCOCs.

7.5.1 US EPA Methods for Risk Characterization

This risk characterization presents a separate evaluation of noncancerous and cancerous effects. US EPA methods distinguish noncancerous from cancerous effects because organisms typically respond differently following exposure to noncarcinogenic or carcinogenic agents. The outcome of this comparison is used to determine whether the constituent concentrations detected in environmental media at the unit may be associated with adverse effects on the health of humans potentially exposed to unit-related constituents.

The risk characterization requires that the potentially toxic effects associated with exposures to each of the constituents of potential concern be considered in combinations with respect to environmental media and exposure routes. As described in the exposure assessment, it is reasonable to assume that the current and/or future receptors could be exposed to constituents of potential concern through direct contact or exposure to unit *soils, groundwater, sediment, surface water, or dust/vapors*. Thus, it is indeed reasonable to combine the hazards and risks from environmental media and exposure routes to develop a receptor total risk estimate.

The potential noncarcinogenic hazards and carcinogenic risks are assessed quantitatively by evaluating exposure estimates with respect to available toxicity values for the constituents of potential concern. *In addition, a methodology for estimating the radiation dose equivalent to humans from potential exposure to radionuclides is provided in guidance (EPA 1989). The estimates of dose equivalent for the [waste unit] are presented in Appendix [X] and may be used for comparison with radiation protection standards and criteria.*

7.5.1.1 Evaluation of Noncarcinogenic Hazards

The hazard of adverse noncarcinogenic effects from constituent exposure is expressed in terms of a hazard quotient (HQ) for a particular exposure route. The exposure route hazard quotient (ERHQ) is the ratio of the estimated chronic daily intake of a COPC to a reference dose level (RfD). RfDs were previously described in Section 7.4. To evaluate exposure from more than one noncarcinogen, the constituent-specific ERHQs are summed in a given environmental medium to obtain the exposure route hazard index (ERHI). The ERHIs may then be summed to determine the total medium hazard index (TMHI) (i.e., ingestion, dermal contact, and inhalation of dust for surface soils). In order to estimate the total cumulative hazard index (TCHI) for each receptor, the TMHIs may be combined across all relevant media (i.e., soil, groundwater). The hazard estimates associated with homegrown produce are presented separately (Appendix *[X])* and are not summed with the hazard estimates from the other media.

If the TMHIs are greater than or equal to 1, the ERHQs from each media are summed according to target organs. This value, known as the total organ hazard index (TOHI), is used to identify the noncarcinogenic preliminary COCs.

7.5.1.2 Evaluation of Carcinogenic Risks

Cancer risks are estimated as the incremental (unit-specific) excess probability of an individual developing cancer over a lifetime as a result of pathway-specific exposure to radionuclides and chemical carcinogens (i.e., incremental or excess individual lifetime risk over the course of a 70-year lifetime for chemicals and a 50-year lifetime for radionuclides). This value is calculated by multiplying the average daily intake over a lifetime by the CSF for the constituent. To account for simultaneous exposure to multiple carcinogens through a given exposure route (i.e., ingestion), the risks calculated for each individual carcinogen in that medium are summed to obtain the exposure route risk (ERR). The ERRs for each exposure route in a particular medium may then be summed to reach a total medium risk (TMR) (e.g., ingestion, dermal contact, and inhalation of dust for soils). For determination of the TMR, the cancer risk estimates for radionuclides are presented along with, but are not combined with the cancer risks for nonradioactive constituents. However, the chemical and radionuclide TMRs are combined across all relevant media to estimate the total cumulative risk (TCR) for each receptor (i.e., soil, groundwater). As noted above, the risk estimates associated with homegrown produce are presented separately (Appendix *[X]*) and are not summed with the hazard estimates from the other media.

7.5.1.3 ***US EPA Risk Characterization Method for Lead***

Health effects associated with low-level lead exposures include reproductive effects, neurological effects, and learning disorders. At the present time, toxicological studies indicate that there may be no threshold of exposure below which adverse effects do not occur. Given the uncertainty surrounding an acceptable exposure, below which there would be no adverse effects for lead, US EPA has withdrawn the RfD for lead. In response to these recent developments, the Centers for Disease Control (CDC) have established a guideline for acceptable blood lead levels in children of 10 ug/dl of blood (lowered from 25 ug/dl).

Direct monitoring of blood-lead levels in exposed populations is not available for the investigation of the *[waste unit]*. Therefore, the risk characterization for lead is based on an alternative method using a biokinetic model developed by US EPA for assessing the significance of exposures to children. The Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK), also known as LEAD 0.99 (EPA, 1994x), has been developed by the US EPA to estimate blood lead levels in children based upon uptake originating from various sources in the environment. It is not applicable to adults. The LEAD 0.99d model includes default exposure parameters, which may be reasonably substituted in the absence of site-specific data. Conclusions drawn from the evaluation of children in a residential setting are believed to be adequately protective for adults in a residential setting. A different model is also used for evaluating lead exposure to workers, recently developed and published by US EPA (“Recommendation of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil”, EPA, 1996). This model provides a method for assessing the significance of lead exposure to the fetuses of working adult women..

The current US EPA limit for lead exposures is based upon the proposed benchmark blood level concentration developed by the CDC. Any values below this limit should have a 95 percent probability that blood-lead levels will not exceed 10 ug/dl for the most sensitive children within the age group 0 to 6 years. Stated another way, this limit provides protection for at least 95 percent of the target population. In the risk assessment for the *[waste unit]*, this benchmark has been applied to both the adult and child models.

7.5.2 Interpretation of Human Health Risk Assessment Results

COCs are the individual COPCs that significantly contribute to the total media risk or hazard. As discussed below in Sections 7.5.3 and 7.5.4, COCs are segregated into primary and secondary COCs and are evaluated further during the uncertainty evaluation in Section 9.0. Remedial goal options (RGOs) are determined in Section 10.0 for the RCOCs retained following the uncertainty evaluation.

7.5.3 Significance of the Noncancer Effects

For noncancerous effects, a HI greater than 1 has been defined as the initial level of concern for adverse noncarcinogenic health effects (EPA, 1989*[x]*), and an HI of 3 has been defined as an additional higher level of concern. For noncarcinogens, these health effects are evaluated for the target organ within a given medium.

<u>Primary noncancer COCs</u> are designated as constituents with individual HQs greater than or equal to 0.1 that are associated with an exposure medium with a TOHI greater than or equal to 3.

<u>Secondary noncancer COCs</u> are designated as constituents with individual HQs greater than or equal to 0.1 that are associated with an exposure medium with a TOHI greater than or equal to 1 but less than 3. Note that constituents with individual HQs less than 0.1 are not designated as COCs.

7.5.4 Significance of the Cancer Risks

Cancer risks are evaluated using the US EPA target range of 1×10^{-4} to 1×10^{-6} for incremental cancer risk. Risk levels above 1×10^{-4} are generally considered significant. Cancer risks between 1×10^{-4} and 1×10^{-6} are generally considered to represent exposure levels requiring a risk management decision regarding the need for remediation. Cancer risks less than 1 x 10^{-6} are considered to be of little concern in terms of evaluating human health.

If the total media risk (TMR) is greater than or equal to 1 x 10^{-4}, then individual COPCs with cancer risks greater than or equal to 1 x 10^{-6} are identified as <u>primary carcinogenic COCs</u>. If the TMR is greater than or equal to 1 x 10^{-6}, but less than 1 x 10^{-4}, then individual COPCs with cancer risks greater than or equal to 1 x 10^{-6} are identified as <u>secondary carcinogenic COCs</u>.

If there are no individual constituent cancer risks of greater than 1 x 10^{-6}, then no carcinogenic COCs are identified.

7.6 Human Health Risk Assessment Results

Chemical cancer risks and health hazards are estimated for each COPC for each exposure route and receptor based on US EPA guidance (EPA 1989). Carcinogenic risks and noncarcinogenic hazards are summarized across exposure routes and media for each receptor at the *[waste unit]*. *For example, the risks to the known on-unit worker resulting from the ingestion of, dermal contact with, and inhalation of soil COPCs are combined to estimate a total risk for nonradioactive carcinogens from soil. The totals for each medium are then summed to obtain a total risk value that includes all reasonable pathways for each receptor*. Risks resulting from potential exposure to radionuclides are assessed two ways: (1) a numeric risk comparable to the risk derived for non-radiological carcinogens is derived, and (2) a dose equivalent is derived which may be compared with radiation protection standards and criteria.

The RME risk estimates for current and future land use for human receptors at the *[waste unit]* are discussed in the following sections. Tables 7.6.1-*[X]* and 7.6.1-*[X]* provide a summary of carcinogenic risk and noncarcinogenic hazard for the exposure routes and receptors identified for quantitative evaluation. Detailed risk and hazard calculations are provided in Appendices *H-M*. Dose equivalents are provided in Appendix *[X]*.

7.6.1 Human Health Summary of Receptor Risks and Hazards

7.6.1.1 <u>Results for Current Land Use for "Subunit A"</u>

[Unit-specific - example provided; when multiple exposure groups are evaluated separately, i.e., such as a pipeline and basin, each should be discussed separately]

Under current land use, only one receptor population – the known on-unit worker – is potentially exposed to constituents at the (unit name). *The primary exposure medium for this receptor is (fill in the blank).*

7.6.1.1.1 Carcinogenic Risk (Nonradiological)

The estimated surface soil TMR for nonradionuclides (1 x 10^{-x}) is less than/greater than 1 x 10^{-6} indicating that nonradiological carcinogenic risk is significant/insignificant at the "Subunit A" under current land use conditions.

7.6.1.1.2 Noncarcinogenic Hazard.

The estimated surface soil TMHI (#.###) is above/below 1, indicating that noncarcinogenic hazard is significant/insignificant at the "Subunit A" under current land use conditions.

7.6.1.1.3 Radiological Risk

The estimated surface soil TMR for radionuclides (1 x 10^{-x}) is less than/greater than 1 x 10^{-6}, indicating that radiological carcinogenic risk is significant/insignificant at the "Subunit A" under current land use conditions.

7.6.1.2 <u>Results of Future Land Use for "Subunit A"</u>

[unit-specific - example provided]

Under the future land use scenario, two receptor populations – the hypothetical on-unit worker and the hypothetical on-unit resident (adult and child) – *could be exposed to constituents at "Subunit A."* The on-unit industrial worker could be exposed to *surface soil*, *subsurface soil if excavation occurs, and groundwater if it is used for drinking water [and others as applicable]*. The on-unit resident could be exposed to the same media, *as well as to surface water and sediment in the stream while wading or playing in these areas [or other scenarios as applicable]*. For the purpose of estimating total cumulative risk and hazard from exposure to several media, the following cases were evaluated – each addressing reasonable combinations of exposure media:

- *Future Industrial Worker (Surface Soil/Groundwater)*
- *Future Industrial Worker (Subsurface Soil/Groundwater)*
- *Future Resident (Surface Soil/Groundwater/Surface Water and Sediment at the Stream)*
- *Future Resident (Subsurface Soil/Groundwater/Surface Water and Sediment at the Stream)*

[add discussions for additional subunits]

7.6.1.2.1 Carcinogenic Risk (Nonradiological)

<u>Hypothetical On-Unit Industrial Worker</u>

The estimated surface soil TMR for nonradionuclides (1 x 10^{-x}) is less than/greater than 1 x 10^{-6} indicating that nonradiological carcinogenic risk is significant/insignificant at the "Subunit A" under current land use conditions.

<u>Hypothetical On-Unit Resident</u>

The estimated surface soil TMR for nonradionuclides (1 x 10^{-x}) is less than/greater than 1 x 10^{-6} indicating that nonradiological carcinogenic risk is significant/insignificant at the "Subunit A" under current land use conditions.

7.6.1.2.2 Noncarcinogenic Hazard

{Repeat sections for each receptor as appropriate}

7.6.1.2.3 Radiological Risk

{Repeat sections for each receptor as appropriate}

7.6.2 Human Health Risk Assessment Summary

7.6.2.1 Summary of Total Cumulative Risk

The total cumulative risk (TCR) is determined for each receptor (e.g., industrial worker and resident) by summing the TMRs. In accordance with US EPA's *Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination* (EPA, 1997*[x]*), cancer risks from both radiological and non-radiological contaminants should be summed to provide risk estimates for receptors exposed to all types of carcinogenic contaminants. As explained in Section *[insert correct section number]*, radionuclide and chemical carcinogenic risks are tabulated separately for the TMR to determine COCs. However, the radionuclide and chemical carcinogenic TMRs are combined to determine a single TCR value for comparative and risk management purposes.

As described earlier, ingestion of fruits and vegetables was quantified for the future on-unit resident receptor, although there is a high level of uncertainty associated with modeling soil-to-plant uptake. Because the results are considered highly uncertain, they were not included in the TCR summaries. Tables in Appendix *[x]* provide the noncancer hazard and cancer risk estimates for ingestion of tuberous vegetables, leafy vegetables, and fruits grown in surface soil and subsurface soil at the *[list all of the subunits]*.

Noncancer hazard estimates that equal or exceed 1 are associated with the following media:

- *[location & medium]*
- *[location & medium]*
- *[location & medium]*

Cancer risk estimates that equal or exceed 1 x 10^{-6} are associated with the following media:

- *[location & medium]*

- *[location & medium]*
- *[location & medium]*

[Add additional explanations as needed similar to the following example: It should be noted that these estimates also exceeded 1 x 10^{-4}, primarily due to Strontium-90 in the surface soil. Radionuclide dose estimates from produce ingestion exceed 30 mrem/yr for surface and subsurface soils at all of the exposure subunits].

Tables 7.6.1-*[X]* through 7.6.1-*[X]* provide summaries of the total risk across all media and exposure routes. In addition, a summary is presented below.

7.6.2.1.1 Known On-Unit Worker

<u>Surface Soil</u>

The total carcinogenic risk for the known on-unit worker based on the summation of the TMR is [1 X 10^{-x}]. The TMR for chemical and radionuclide constituents is [1 X 10^{x}] and [1 X 10^{-x}], respectively.

7.6.2.1.2 Future Industrial Worker

<u>Surface Soil/Groundwater</u>

The total carcinogenic risk for this receptor based on the summation of the TMR is *[1 X 10^{-x}]. The total risk across all media for chemical and radionuclide constituents is [1 X 10^{x}] and [1 X 10^{-x}], respectively.*

<u>Subsurface Soil/Groundwater</u>

The total carcinogenic risk for this receptor based on the summation of the TMR is *[1 X 10^{-x}]. The total risk across all media for chemical and radionuclide constituents is [1 X 10^{x}]and [1 X 10^{-x}], respectively.*

7.6.2.1.3 Future On-Unit Resident

Surface Soil/Groundwater/Surface Water and Sediment

The total carcinogenic risk for this receptor based on the summation of the TMR is *[1 X 10^{-x}]. The total risk across all media for chemical and radionuclide constituents is [1 X 10^{x}] and [1 X 10^{-x}], respectively.*

Subsurface Soil/Groundwater/Surface Water and Sediment

The total carcinogenic risk for this receptor based on the summation of the TMR is *[1 X 10^{-x}]. The total risk across all media for chemical and radionuclide constituents is [1 X 10^{x}] and [1 X 10^{-x}], respectively.*

7.6.2.2 Summary of Risk from Multiple Units

[This section is applicable only if multiple units within an operable unit were evaluated separately for the selection of COCs, but were then combined to determine risk value for the operable unit. An example is provided below].

An additional total estimate of hazards and cancer risks is provided for the [single unit name, i.e. Pit Area] and the [single unit name, i.e. Pipeline]. This analysis is used to address concerns regarding the proximity of the [2] units and uncertainty regarding the potential for exposure at either location. The purpose of this analysis is not to re-characterize the risks, but rather to determine whether the evaluation of multiple exposure units would result in a different result or conclusion.

The results of this analysis are provided in Tables 7.6.1-[X] through 7.6.1-[X]. In addition, a summary is presented below.

7.6.2.2.1 Known On-Unit Worker *[unit-specific]*

7.6.2.2.2 Hypothetical Industrial Worker *[unit-specific]*

7.6.2.2.3 Hypothetical On-Unit Resident *[unit-specific]*

7.6.3 Human Health Constituents of Concern

COCs in human health risk assessments are defined for certain constituents with individual cancer risk estimates greater than 1 x 10^{-6}, or a HQ greater than 0.1. Tables 7.6.2-*[X]* through 7.6.2-*[X]* provide summaries of the primary and secondary human health COCs that may trigger the need for remedial action.

COCs are not necessarily a threat to human health or the environment, but they do exceed the evaluation criteria established by the US EPA. Therefore, these COCs are important considerations during the risk management process. COCs that are retained for further remedial evaluation following the uncertainty evaluation are identified as refined COCs in Section 9. RGOs are derived for the refined COCs in Section 10.

7.6.4 Human Health Risk Assessment Uncertainty Discussion

[Unit-specific - examples provided below. Add to or delete uncertainty sections as appropriate. For example, radionuclide discussions should be removed if no rads are present at the site.]

Uncertainty will always surround estimates of environmental concentrations at waste units. Uncertainty in the analytical data may be linked to sample density and distribution, collection procedures in the field, seasonal fluctuations, and accuracy of the sample analyses.

Sample collection procedures are established to reduce uncertainty surrounding the sample results. Standard QA/QC measures (e.g., proper decontamination of equipment and collection of trip blanks, field blanks, and matrix spike/matrix spike duplicates [MS/MSDs]) are followed to reduce uncertainty associated with the analytical data. The uncertainty associated with sample collection procedures has the potential for either over- or underestimating risks to receptors.

Uncertainty may also be introduced the laboratory. Standardized procedures are followed in the laboratory to reduce this uncertainty. These standardized procedures may include the use of surrogate spikes to monitor constituent recovery, internal standards to monitor instrument sensitivity, and laboratory blanks to determine whether laboratory preparation has introduced contamination to the sample. These measures are explained in the data quality assessment for the *[waste unit] (References*).

Different types of uncertainty have been identified regarding the exposure assessment:

- Scenario Uncertainty — in which information needed to define the exposure scenario or pathway is missing or incomplete,

- Model Uncertainty — in which not all assumptions in model variables can be quantified, and,

- Parameter Uncertainty — in which not enough information exists to quantify an exposure variable or parameter.

Many of the exposure parameters used in risk assessment are default values recommended by US EPA. These default parameters, which are generally conservative, do not necessarily reflect actual behavior and have been used in the absence of site-specific information. In addition, assumptions regarding the future land uses are speculative. In attempting to predict future exposures, assumptions must be made concerning contaminant fate and transport, future site activities, and receptor behavior. In particular, it was assumed that contaminant concentrations will be the same in the future as at present, and that the contaminants themselves are immobile.

Model uncertainty arises from the use of models to predict the uptake of contaminants in soil into plants grown in the contaminated soil. Humans or animals as food may then eat such produce. Additional models can be used to further predict the transfer of contaminants along the food chain. In this way a soil-to-plant model could be used in conjunction with soil-to-animal and plant-to-animal uptake models to predict the uptake of contaminants into animals eating the contaminated plants.

Uncertainty is inherent in each step of the food chain uptake models. Such models are based on studies of plant and animal uptake of constituents into the receptor of interest, and are thus reliant upon a set of conditions that were present in the study environment. Precipitation and other weather-related factors, soil and water chemistry, and factors that were apparent in the uptake study may or may not relate well to the conditions present at the site of interest. Uncertainties resulting from the use of food chain uptake models are likely to be considerable.

The uncertainty associated with the exposure assumptions used in the risk assessment is moderate, and most likely overestimates the actual risks.

7.6.4.1 Uncertainty in the COPC Selection Process

The COPC selection process reduces the number of constituents carried through the risk assessment. Briefly stated, the focus is to eliminate chemicals that have been rejected or are otherwise unusable based on the data quality assessment, to disregard the contributions of naturally-occurring inorganic and radiologic constituents if they are indistinguishable from background, and to disregard constituents that are well below RBCs or RBAs for various media.

Uncertainty introduced by the COPC selection process is likely to be minimal. The most significant effect on the risk estimates will most likely result from disregarding risks from naturally occurring constituents that are not site-related. In some cases, the risks from exposure to background levels of naturally occurring constituents are considerably, high enough for COCs to be identified for the background. Cleanup of uncontaminated media is clearly not desirable or required at disposal sites, and the background screen is an attempt to avoid such a situation.

7.6.4.2 Uncertainty in the Background Screening Step

The background screen was conducted using a method recommended by US EPA Region IV. The method is very simple, and is based on comparing the maximum concentration of constituents detected at the unit to a value of 2X the mean concentration of the same constituent in the background data set. This approach does not take into account type of distribution (e.g., normal, lognormal, non-parametric). The value of 2X the mean is selected as an arbitrary representative of the spread (variability) of the background sample data. These factors increase the uncertainty in the effectiveness of detecting naturally occurring levels of constituents.

Soil samples representative of background were collected from locations that are believed to be adequately representative of background for the SRS. As such, the uncertainty related to the location of the background samples appears to be minimal.

7.6.4.3 Uncertainty in the Sample Locations

Uncertainty can be introduced to the risk assessment through the sampling data. The risk assessment uses sample data that may have been collected for a purpose other than characterizing exposures. Soil samples are typically collected from areas that are suspected of being contaminated. For example, soils may be collected from a small stained area of 100 square feet. The samples are useful for defining the nature and extent of contamination, but they are not good representatives of the overall exposure that may be encountered in an area of, for example, a residential yard. Use of the sample data would result in an overestimate of the average hazard and risk for the yard. Samples of this type might be useful for characterizing exposure to a hotspot. It is highly unlikely, however, that a person will spend the majority of his or her time within that small area. Once again the risk estimates would be overestimated. Given the nature of RFI/RI Work Plans to focus sample collection areas of contamination, it is unlikely that the bias will results in underestimation of hazard and risk.

At the [waste unit], the areas of contamination vary from well-defined, fairly small areas, such as at the new and old seepage basins, to areas in which contaminants tend to be dispersed over increasingly large areas, such as at the Outfall Delta and the downgradient swamp area. The contamination within small areas such as the seepage basins is easier to find in comparison to the swamp area. The density of the samples is also greater for the smaller areas of contamination. It is simply impractical to sample the larger areas of potential contamination with the same relatively high density of samples. Because the distance between samples increases in the larger exposure units, there is a greater potential to overlook small hotspots. Inspection of the maps showing the sampling locations for the [waste unit] does indicate, however, that the number of and the coverage afforded by the samples is based on a rigorous sampling effort. Uncertainty in this regard should be minimal within the constraints of characterizing large areas.

7.6.4.4 Uncertainty in the Exposure Point Concentrations

The current guidance for determining the exposure point concentrations in environmental media is based on highly conservative statistical assumptions. The 95 UCL is purposely intended to produce a high estimate on the mean concentration. The 95 UCL, when applied to typical sample data such as the data collected at the [waste unit], quite often results in estimates that are representative of the high end of the distribution of concentrations, not the central portion in which the mean exists. In fact, the UCL often exceeds the maximum, in which case the maximum observed result is substituted for the (95 UCL). The overall result in terms of uncertainty is a pronounced bias toward overestimation of the mean concentration. This in turn has a directly proportional effect on the risk estimates.

The activity for some radionuclides was reported as negative values. Depending upon the proportion of negative values in the data set, the value used as the exposure point concentration is sometimes negative. The use of a negative concentration term results in negative cancer risk estimates, which are nonsense in terms of expressing a probability of cancer effects. For example, the cancer risks for cobalt-58 and zinc-65 in the soil at the Outfall Delta are negative values (see Table X). The effect of a negative value on the sum total cancer risk is to subtract the negative value from the total. The overall effect on uncertainty of including negative activities is a tendency to underestimate cancer risk and committed effective dose equivalent. For the [waste unit], the values in the cancer risk column are very small compared to the values for the other constituents, so such an effect is very small.

The solution to this problem is fundamentally an issue of sample analysis and data validation. A negative radioactivity may result from numerical manipulations in which portions of the detected activities are subtracted out. Thus, a value of less than zero is an artifact that actually represents near-zero radioactivity. One approach for better handling negative values for radioactivity could be to flag them as such and report them as near-zero or zero values before inclusion in the risk assessment.

7.6.4.5 Uncertainty in Land Use and the RME Exposure Assumptions

Uncertainty is introduced in risk assessment through the use of unrealistic and biased exposure assumptions. These exposure assumptions are likely to overstate the hazard and risk. A clear and simple example of unrealistic exposure assumptions is the assumption of residential land use when it does not or is unlikely to occur. The same could be said for a full-time industrial scenario in cases where land use remains undeveloped, or the potential exposure intensity and frequency remains low.

RME exposure assumptions are intentionally biased toward the high end of possible outcomes, erring on the protective side. This protectiveness will of course directly affect the resulting risk estimates in that they will tend to be overstatements of the actual or most likely hazard or risk. In order to provide some perspective regarding the conservative nature of the RME estimates, a set of more realistic estimates have been provided as a companion to each RME estimate. These estimates are based on assumptions and parameters intended to yield central tendency (CTE) hazard and risk estimates. In general, CTE estimates are less stringent than RME estimates.

Since CTE estimates are based on the central tendency, they are considered to represent more likely the outcomes as opposed to the more conservative RME estimates.

Although CTEs are intended to present useful information to decision-makers, it is worth noting that in most cases environmental decisions are based on the RME estimates. The CTE could, however, be used in certain cases to provide justification for exceptions to custom adherence with the RME.

7.6.4.6 Uncertainty in the Toxicity Values

The toxicity values used in the risk assessment are also a source of uncertainty. Toxicity values are usually based on experiments conducted on non-human species. In such cases, interspecies extrapolations are used to adjust the toxicity values for the experimental animal to values appropriate for application to humans. These adjustments are made with the assumption that an effect observed in the test organism would have a lower threshold in humans than in the test species. Differences in metabolism between animals and human may or may not be well represented in the factors used to make the interspecies extrapolation, for example. Furthermore, the mode of administration used in an experiment may differ from that encountered in the environment. For example, in an experiment a toxin may be administered to an animal via gavage using corn oil as a vehicle, whereas in the environment such an exposure is not likely to occur. Therefore, the mode of administration used in the experiment may not closely represent the exposure that occurs in the environment (e.g., via ingestion of soil).

7.6.4.7 Uncertainty in the Toxicity Data

The greatest uncertainty regarding toxicity information for this risk assessment is in the use of the provisional RfDs. There is no US EPA-verified toxicity value for *iron, PCE, TCE*, although there is a provisional RfD developed by US EPA's NCEA. The significance of findings based on provisional toxicity values should be tempered by the understanding the provisional RfD is not a US EPA-verified toxicity value, and could be so uncertain that it may not provide an adequate basis for decision-making.

Human health effects resulting from exposure to iron have been evaluated using a provisional oral RfD. US EPA's provisional toxicity values are not intended for general use in risk assessments, and represent a lower level of quality and certainty than verified toxicity values.

The use of provisional toxicity is thus a significant source of uncertainty. Because of this uncertainty for iron, oral exposures have been evaluated in the risk assessment, but a dermal toxicity value based on the provisional oral toxicity value has not been developed.

In some cases, surrogate toxicity values or toxic equivalents have been used. Examples of the use of surrogate toxicity values include the following substitutions: *PAHs (pyrene, for noncancer effects), endrin ketone (endrin), endosulfan sulfate (endosulfan), chromium (hexavalent chromium), mercury (inorganic mercury), and thallium (thallic oxide)*. The overall effect on the uncertainty introduced through these substitutions is unclear. Such substitution could result in a tendency toward higher hazard and risk estimates, when compared to not evaluating these substances at all. Alternately, if the true toxicity of the detected substances is greater than the substituted value, then there is some potential for underestimating the hazard or risk.

7.6.4.8 Uncertainty in Detection Limits that Are Higher than Some Detects

In considering the detection limits for soil samples, there are some cases in which a given analyte has a detection limit in some samples that is greater than the reported value in other samples. In these cases, the detection limit may be higher than is desirable to characterize risks, since one-half the detection limit is often used. Relatively high detection limits can occur as a result of moisture variations in the soil sample, or from the need to dilute highly concentrated samples. In some cases it may be appropriate to eliminate very high detection limits from the data set used in the risk assessment, but outside of such special occasions, variable detection limits are usually included in the data set. The overall effect on uncertainty is unclear, since the true concentration of a relatively high nondetect could be either higher or lower than the average of the data set.

7.6.4.9 Uncertainty of the Natural Abundance of Radioisotopes

The majority of the COCs identified for the soil and sediment at the [waste unit] are radionuclides. Some of the radionuclide COCs are naturally occurring and some are man-made. They may relate to processes that have occurred at the unit, or to the natural characteristics of the soil. Radionuclides could also originate from anthropogenic sources that are not related to the operation of the [waste unit].

An important indication of whether or not a radioisotope is unit-related is the relative abundance of radioisotopes and their decay products. First, the activities of the primary radioisotope and its daughters are inspected to determine if they are present at activities indicating secular equilibrium. For example, if daughters with decay half-lives of much longer than 30-40 years are found at activities that are similar to the parent, this would indicate that those radioisotopes have been present for a period of time that predates operations at the [waste unit]. Such radioisotopes would appear to be naturally occurring. If, however, the entire decay series has half-lives of less than 30-40 years, and daughters are present at similar activities to the parent isotope, then the source could be either natural or anthropogenic. At some waste units some of the most important COCs are thorium-232 and its daughters, which have half-lives of less than 30-40 years. Thorium and its daughters are known to be process-related at the Savannah River Site. The uncertainty in this case is to distinguish between naturally occurring and anthropogenic sources of thorium and its daughters, which could vary from location to location. This uncertainty is discussed in further detail in Section 9.1.3, in which the COCs identified in Section 7.2 are refined to include only those for which there is evidence that the COC is related to operations at the unit.

7.6.4.10 (Additional uncertainty sections as appropriate)